

# TTIP

## I. Regulatory issues :

### Greater regulatory convergence:

- Ø a built-in agenda allowing for progressive greater regulatory convergence over time.
- Ø a Working Group on Pharmaceutical and Medical Devices as platform to discuss implementation issues and address joint approaches to future compatibility topics.

### Single development plans

- Ø for submission in EU&US for pediatrics;
- Ø extend the current EMA/FDA parallel SA
- Ø adopt the EMA/FDA pilot project for parallel assessment of Quality by design (QbD) application
- Ø address duplicative clinical testing requirements (via revision of ICH E5)

### Other areas of convergence

- Ø establish harmonized list of clinical trial result data fields & agree on which may be disclosed to public (uniform protection of confidential commercial info & trade secrets)
- Ø develop therapeutic area guidelines (beginning with specific treatment areas)
- Ø EU and US to ensure that national/regional coding systems are based on common standards for the use of unique identifiers, developed using non-proprietary, harmonised international standards.
- Ø add a pharmacovigilance cluster to conduct work on post-marketing testing & risk management requirements
- Ø establish common framework & methodology for benefit-risk assessment, but retaining authority to make different risk assessment judgments
- Ø mutual recognition of GMP inspections

## II. IPR :

- Ø PhRMA: seek patent term adjustments for patent office delays in the EU
- Ø PhRMA: seek forms of patent linkage in the EU
- Ø EU/US aligned approach re disclosure of clinical trials data (impact on commercial opportunities in third countries should also be considered)

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- Ø Harmonization on the grace period
- Ø EU/US systems should be open to further adaptation to incentivize research into unmet needs
- Ø Include commitment to shared principles regarding patentability standards
- Ø Extension of data exclusivity(DE) on biologics in EU up to 12 years (*despite in US it is 4ys DE and 8ys Market Exclusivity*)
- Ø Establish a benchmark for not limiting the use of trademarks other than to protect public health

## III. Market Access & Transparency:

- Ø P&R policies should take into account innovation
- Ø when products are grouped for P&R purposes, it should only take into account bioequivalent products
- Ø when external reference pricing, only countries that are similar in terms of their socio-economic level, purchasing power, populations, disease burdens and health care system should be taken into account; bailout countries while they are undergoing fiscal restructuring programmes should be excluded from any referencing
- Ø any reimbursement controls/determinations should apply only to products dispensed and reimbursed in that Party
- Ø To avoid that pricing & reimbursement (P&R) policies hamper trade between EU/US
- Ø include a pharma annex on P&R policies that promote transparency principles in processes & and reward innovation
- Ø Procedural safeguard in government P&R
- Ø specified time-limits for pricing and/or reimbursement decisions
- Ø individual decisions containing a statement of reasons based on objective and verifiable criteria provided to applicants
- Ø legal remedies for applicants

## IV. Other issues:

- Ø **Public Procurement:** building on GPA, a comprehensive chapter with rules on transparency & non-discrimination of public proc. practices at federal & sub-federal level (offensive interest for EU)

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- Ø **Customs:** full liberalization of tariffs and pursuit of simplified and rational RoO based on common defined chemicals & pharmaceutical processing activities
- Ø **Third countries:** coordinated approach for trade policy objectives in third countries: joint principles on regulatory harmonization, transparency measures, IP and tariff elimination and coordinated approach to be leveraged at multilateral level when feasible: WTO, OECD, ICH, WIPO